for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 40 FR 28052, July 3, 1975; 41 FR 2384, Jan. 16, 1976; 41 FR 18291, May 3, 1976; 44 FR 67113, Nov. 23, 1979; 45 FR 16471, Mar. 14, 1980; 46 FR 16677, Mar. 13, 1981; 46 FR 60578, Dec. 11, 1981; 46 FR 61071, Dec. 15, 1981; 50 FR 19918, May 13, 1985; 55 FR 11582, Mar. 29, 1990]

## Subpart C—Records and Reports

### § 431.61 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

### § 431.62 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 431, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

## Subpart D—Confidentiality of Information

### § 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in § 314.430 of this chapter.

(c) Notwithstanding the provisions of § 314.430 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

[39 FR 44655, Dec. 24, 1974, as amended at 50 FR 7517, Feb. 22, 1985]

# PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

Sec.



AUTHORITY: Secs. 201, 301, 502, 503, 507, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 353, 357, 371, 381).

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic drugs exempted from certain labeling requirements, see also § 201.150 of this chapter.

### § 432.1 Packaging requirements.

Each antibiotic drug subject to certification under section 507 or 512(n) of the act shall be packaged in immediate containers which shall be of such composition as not to cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be tight containers as defined by the U.S.P., except that if the antibiotic drug is dispensed as an ointment or cream, the immediate containers shall be well-closed containers as defined by the U.S.P. If the antibiotic drug is packaged for dispensing, it may be packaged in combination with a container of a suitable and

harmless diluent approved by the Commissioner.

(a) If it is a sterile preparation, the containers shall be sterile at the time of filling and closing and shall be so sealed that the contents cannot be used without destroying the seal.

(b) If it is intended for parenteral use and the container is glass, it shall be transparent and colorless or light-resistant as defined by the U.S.P. The containers are closed either by fusion or by application of suitable closures, in such manner as to prevent contamination or loss of content. Multiple-dose containers are closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each container shall be filled with a quantity of a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and administration of the labeled quantity or volume, whether administered in single or multiple doses.

(c) If it is dispensed as a tablet, capsule, troche, pellet, or suppository, it may be enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U.S.P., except for the provision that it shall be capable of tight reclosure. The immediate container may contain a dessicant separated from the drug by a plug of cotton or other like material.

(d) If it is dispensed as an ointment or cream, it shall be in collapsible tubes that shall in no case be larger than the 2-ounce size, except:

(1) If it is labeled for institutional use, it may be packaged in immediate containers larger than the 2-ounce size and it may be packaged in immediate containers of glass or plastic; or

(2) If it is an ointment represented for ophthalmic use, it shall be in collapsible tubes which shall not be larger than the ⅛-ounce size.

(e) If it is intended for ophthalmic use, the closure shall be one through which a hypodermic needle cannot be introduced.

[39 FR 18938, May 30, 1974, as amended at 42 FR 44225, Sept. 2, 1977; 44 FR 10377, Feb. 20, 1979]

### § 432.5 Labeling requirements.

(a) If an antibiotic drug is packaged for dispensing:

(1) It shall be labeled in accordance with the requirements prescribed by § 201.100 of this chapter, issued under section 502(f) of the act, unless the regulations pertaining to such drug specifically exempt it from such requirements.

(2) Its labeling shall bear any additional information required for the drug by specific regulations.

(3) Each package shall bear on its outside wrapper or container and the immediate container an expiration date prescribed for the drug by specific regulations; except that in lieu of the expiration date prescribed by specific regulations, a date may be used that is 12, 18, 24, 30, 36, 42, 48, 54, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time. If the specific regulation does not stipulate an expiration period, it shall be as prescribed by this section. If the manufacturer or repacker of the drug has been exempted from the certification requirements, such date shall be the number of months after the month during which the batch was last assayed and released by the manufacturer or repacker. If an expiration date is used that is longer than the minimum date provided for the drug by specific regulations, it may be used only if the manufacturer has submitted information to the Commissioner adequate to prove that the drug is stable for such time.

(b) If it is packaged solely for manufacturing use or for repacking, each package shall bear on its outside wrapper or container and the immediate container, the following:

(1) The number of units or micrograms of activity per milligram or per gram, and the number of grams or kilograms in the immediate container.

(2) The batch mark.

(3) The statement ''Caution: Federal law prohibits dispensing without prescription.''

(4) The statement ''For manufacturing use,'' ''For repacking,'' or ''For manufacturing use or repacking,'' and, if it is not sterile, the statement ''nonsterile.''

(5) The required expiration date.

(c) The expiration date prescribed for a drug by the regulations in this chapter may be omitted from the label of the immediate container if such container contains a single dose and it is packaged in an individual wrapper or container that bears the date prescribed.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

### § 432.9 Labeling of antibiotic drugs intended for export.

(a) Antibiotic drugs subject to certification under section 507 of the act and intended for export will be certified notwithstanding failure to meet the labeling requirements of the applicable sections if the labeling used for such drugs meets the following conditions:

(1) It has been approved before use by the Government authorities of the country to which the drugs are intended for export; and

(2) Such labeling represents that such drugs are for use only in those conditions for which they are certified for domestic distribution.

(b) The legend ''Caution: Federal law prohibits dispensing without prescription'' might be inappropriate on antibiotic drugs exported from the United States, since their sale may or may not be so restricted under the laws of the country of destination. The Food and Drug Administration would not object to a slight modification of the wording to read, ''Caution: Federal (U.S.A.) law prohibits dispensing without prescription,'' by a manufacturer who wishes to market a drug under the same label both in domestic and foreign commerce.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

### § 432.20 Declaration of potency.

Wherever the potency of an antibiotic drug included in the regulations in this chapter is expressed in terms of weight, such potency shall be equivalent to that contained in the same weight of the master standard of the drug.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

## PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

### Subpart A—General Provisions

Sec.



### Subpart B—Exemptions for Which an Application or Notice Is Required



### Subpart C—Specific Use Exemptions



### Subpart D—Records and Reports



AUTHORITY: Secs. 502, 505, 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 355, 357).

SOURCE: 39 FR 18939, May 30, 1974, unless otherwise noted.